Attorney Docket # 5434-16 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Tom MINER, *et al.*
Serial No.: 10/768,760
Filed: January 29, 2004
For: Intravenous Delivery System

Examiner: Osinski, Bradley J.
Group Art: 4111

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

SIR:

This is a Request for a Pre-Appeal Brief Review. The present request is filed concurrently with a Notice of Appeal. No amendments are being filed with this request.

This Notice of Appeal and Request are filed in response to the second non-final Office Action dated July 9, 2008. Claims 1-55 are pending. Claims 1, 22, 24, 31, 40, 43, 49 and 55 are independent. Except for claims 22, all claims have been twice rejected. The issue for review is whether the claims are obvious from the combination of primary reference U.S. Patent No. 5,779,674 (Ford), with secondary references U.S. Patent Nos. 4,952,210 (Alchas), 4,571,244 (Knighton) and 6,336,916 (Bormann, *et al.*)

Specifically, it is submitted that the Examiner has failed to point to any reason in the art that would spur one of ordinary skill to modify or combine the references as suggested by the Examiner, particularly where the modifications of the references would require one of ordinary skill to

abandon the express teachings of the primary reference (Ford) and incorporate therein diametrically opposite elements of a secondary reference (Alchas).

The invention is directed to the delivery of an intravenous solution to a patient. Claims 1-23 recite delivery systems for delivering the solution. Claims 24-30 recite means for self-priming such a system; claims 31-42 recite drip chambers for use in such a system and claims 49-51 recite a method for delivering the solution from a container to the patient. Claims 43-48 are directed to the termination end cap of the system which employs a vent similar to that used in the other embodiments.

A description of the background of the invention may be found in the response mailed April 7, 2008 at pages 18-28, and will not be repeated here.

According to each independent claim of the invention (with the exception of claim 43), the drip chamber includes a vent plug or "vent" that is made up of a wettable material that, when dry, allows air to flow *out of* the drip chamber but, when wetted, closes to the passage of air and seals the drip chamber. The vent is disposed in the side wall of the drip chamber. This placement and configuration of the vent allow an intravenous delivery system incorporating the drip chamber to self-prime, and limit the level of solution, *i.e.,* reservoir, that may accumulate in the drip chamber so that a desired spacing will be preserved between the surface of the reservoir and the top of the drip chamber. The spacing is important because it provides for visual inspection of medicament drops as such drops descend in the drip chamber to the reservoir.

The combination of references applied by the Examiner fails to teach or suggest the claimed invention. It would not be obvious for one of ordinary skill in the art to combine the references in the manner suggested by the Examiner and there is no apparent reason to combine the references in the fashion suggested to result in the claimed invention.

The primary reference is Ford, which describes a fluid gas removal drip chamber for use in an IV solution delivery system. Ford's system includes a hydrophobic filter assembly **28** that allows air to exit the drip chamber without allowing fluid to pass therethrough (col. 4, lines 53-58). Assembly **28** includes a hydrophobic membrane **52** and a support structure **53** that is disposed within membrane **28** (col. 4, lines 59-62; Fig. 2). As seen in Fig. 2 of Ford, assembly **28** extends parallel to the side wall of the drip chamber from the top downward toward the reservoir. The placement of filter assembly **28** obscures the dripping of the solution into the drip chamber from certain vantage points (*e.g.*, from the right side as viewed in Fig. 2), which will obscure inspection of the drip rate. Ford teaches that the hydrophobic filter assembly **28** *must* be "vertical" (which includes an angled presentation), but "*not an entirely horizontal hydrophobic membrane*" (col. 7, lines 7-18; emphasis added).

The Alchas patent is directed to a parenteral fluid administration set that includes a vented container assembly **50** having a housing **51** and a chamber **52** for retaining fluid therein. Housing **51** includes a venting means having an aperture **58** covered by an air-permeable, liquid-impermeable element **59** (col. 6, line 53 – col. 7, line 3). Element **59** allows air to enter chamber **52** while preventing liquid from flowing either way therethrough. There is no discussion in Alchas of having the properties of element **59** vary when it is wetted. Container assembly **50** dispenses the solution to be introduced to the patient into an unvented drip chamber **103** by squeezing of the flexible drip chamber (Figs. 8 and 14, *inter alia* – "Also, the squeezing force is repeated to start the flow of fluid from the vented container into the drip chamber as best illustrated in Fig. **14**."; col. 12, lines 33-36). Drip chamber **103** has no vent in it whatsoever and requires user interactions to prime the system -- which is exactly the interaction the present invention avoids (see par. [0034] of applicants' published application).

Bormann, *et al.* describe a priming system for administering parenteral fluids, and teach the importance of venting gas from the drip chamber to provide for ease of monitoring, *etc.* (*see*, generally, col. 1, lines 31-67). The Bormann, *et al.* system uses a vent **3** located in the top of the device **100** similar to Ford. Vent **3** includes a porous medium **10** having liquophobic and liquophilic elements or layers (col. 5, line 62 – col. 6, line 9). Vent **3** allows the passage of air therethrough until it is wetted, at which point it seals device **100** (col. 6, lines 14-17). However, vent **3** does *not* set the reservoir level.

These three references (Ford, Alchas, Bormann) are all generally directed to the same art as is the present invention, and yet they each take an approach that differs markedly from one another, and are inconsistent in their approaches so that one of ordinary skill in the art would not have any reason to combine them.

Ford and Bormann, *et al.*, for example, teach that the vent in the drip chamber must be on the top of the chamber, *not* on the side as claimed. The Examiner apparently concedes this point, as it is Alchas' disclosure that the Examiner uses to show the venting on the side of the drip chamber. However, Alchas' aperture **58** (which the Examiner has likened to the claimed vent in the side of the drip chamber) is not in the drip chamber at all, rather it is in the container *above* the drip chamber. Additionally, the vent in Alchas is intended to allow air to *enter* the container, rather than leave it (col. 7, lines 59-63), and so it is the precise opposite of the claimed invention. It is also does *not* set the reservoir level

The Examiner, without support, however, states that one of ordinary skill in the art would have found it obvious to move the vent of Ford to the side of the drip chamber. As noted above, Ford *expressly* teaches that the vent *must* be vertical, and *cannot be horizontal* (Ford, col. 7, line 15-17). The Examiner provides no basis for concluding that one of ordinary skill in the art

would have any reason to modify Ford in a manner *completely inconsistent with and directly opposite to* its express teachings to move the vent to the side of the drip chamber to allow air to exit the drip chamber, based on a teaching from another patent that a vent *in another element of the system* could be on the side of that element to let air *in*. There is no teaching in either Ford or Alchas that a vent could be placed on the side of the drip chamber to let air *out*, and so it is submitted that no one of ordinary skill in the art could combine the references *and then modify that combination* to provide one. The Examiner has pointed to nothing in the record to support such a radical modification.

Furthermore, Ford expressly teaches that the vent be made of a hydrophobic material. The Examiner argues that Bormann, *et al.* teach that the vent could be made of a wettable material (which is partly hydrophilic), but makes no showing why one of ordinary skill in the art would modify Ford *in a manner completely inconsistent with Ford's teachings* to adopt some of the teachings of Bormann, *et al.* The addition of the Knighton reference overcomes none of these deficiencies.

With respect to claims 43-48, the prior art combination also does not teach the use of a termination end cap having a vent for restricting the flow of solution in a patient conduit of a solution delivery system, wherein the termination end cap includes a wettable vent plug which, when wet, prevents the escape of solution through the vent.

Respectfully submitted,
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